Instruction for Use

Smooth Metallic Wire and Threaded for Bone Fixation

Legends of the symbols used on packaging

REF	Product Code		Avoid exposure to direct sunlight
LOT	Batch Number		Keep Protected of Humidity
	Read the Use Instructions		Caution – Fragile
Material Ss	Stainless Steel (ASTM F138)		Do not use if the packaging is violated
	Manufacturing Date	NON STERILE	Non Sterile
	Single Use Product		Validity term

Product Description:

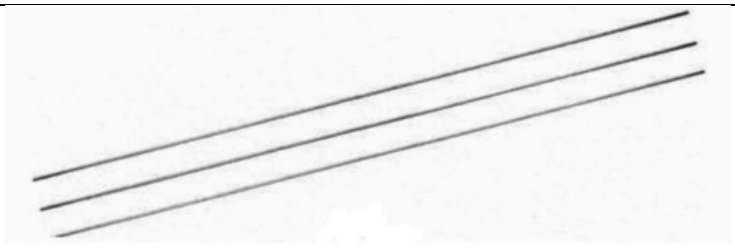
The Smooth Metallic Wire/Threaded for Bone Fixation is manufactured from Stainless Steel, ASTM F138, has cylindrical shape with variation in the diameter and length. It can be presented in malleable or rigid shape with or without thread in its end.

The Smooth Metallic Wire/Threaded for Bone Fixation is presented in the following models:

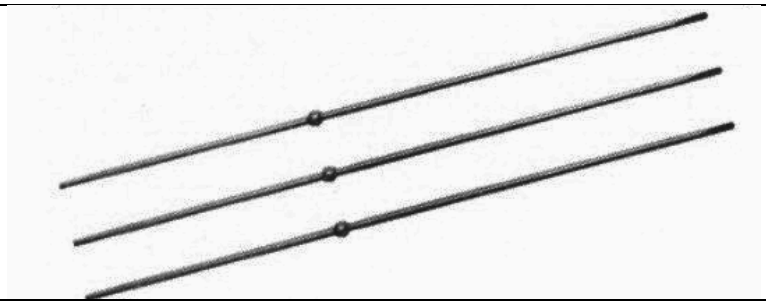
Schanz Pin

Kirschner Wire

Steinmann Wire

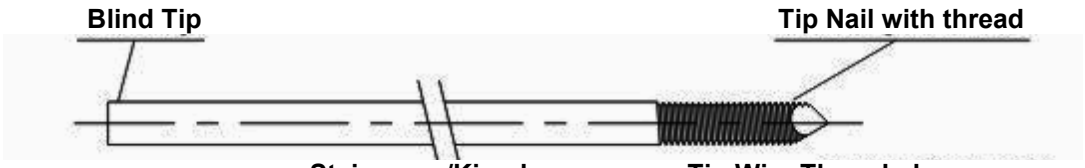


Smooth Wire

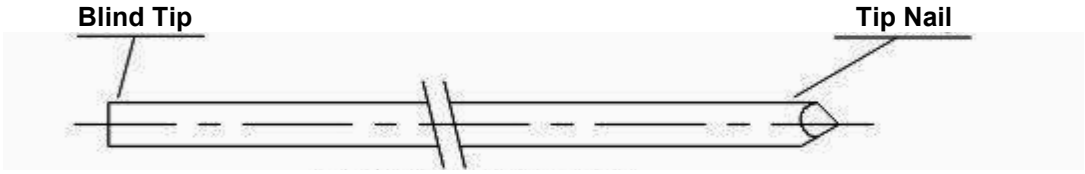


Wire with Olive

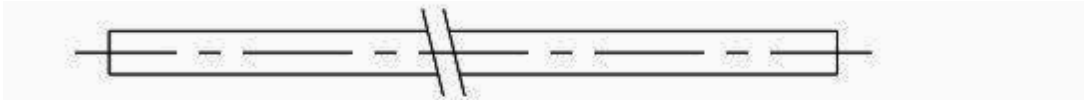
DETAILS OF THE TIPS OF WIRES:



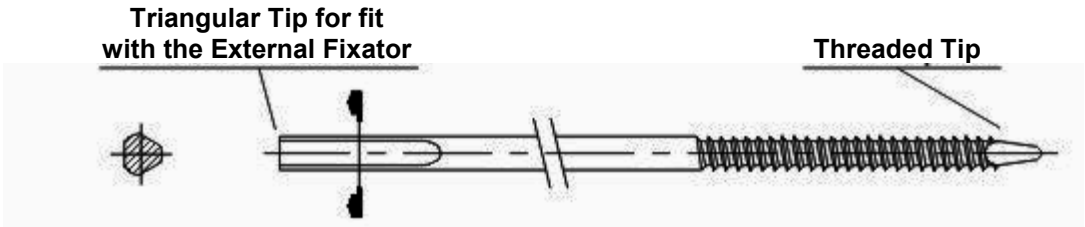
Steinmann/Kirschner **Tip Wire Threaded**



Tip Wire Steinmann/Kirschner



Tip of the Smooth Wires with Olive



Schanz Pin

Composition:

The Smooth Metallic Wire/Threaded for Bone Fixation is manufactured from Stainless Steel, according to the specification: F138 - Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants.

Indication:

This product was developed for fixation and stabilization of fractures.

It is indicated for reducing, alignment, stabilization and fixation of fractures. Its purpose is to provide environment for fracture healing.

The wires are transfixed to the bone, tractioning fragments. They can be used in upper and lower fractures.

Steinmann Wire:

Wire with diameter from 2,0 mm. It is indicated for fractures fixation of femur and tibia. It can be used as reamer and drill guide.

With Thread: Mainly used as a guide for drills and reamers. The thread locks the wire in the bone, preventing the release of the wire.

Smooth: To fix fractures through of the transfixation.
It has a blind tip and another tip in nail shape, which can have thread or not (see figure).

Kirschner Wire: Wire with diameter until 1,8 mm. It is indicated for fixation of fractures in the wrist and humerus. It can be used as reamer and drill guide.

With Thread: Mainly used as a guide for drills and reamers. The thread locks the wire in the bone, preventing the release of the wire.

Smooth: To fix fractures through of transfixation.
It has a blind tip and another tip in nail shape, which can have thread or not (see figure).

Schanz Pin: Wire with thread in one of tips. It is indicated for use with external fixator in fractures of femur, tibia, feet, ankle, humerus, forearm, radio, wrist and phalanx.
It has a tip with thread and the triangular posterior for connection with the fixator (see figure).

Smooth Wire: It is available with diameters of 1,5 mm and 1,8 mm. It has length higher than the other wires. It is indicated for use with external fixator in fractures of femur, tibia, feet, ankle, humerus, forearm, radio and wrist.
It has a blind tip and other tip in diamond shape (see figure).

Wire with Olive: It is available in diameters 1,5 mm and 1,8 mm. It is different of the smooth wire due to olive, used to traction the bone through of the tensioner instrumental, joining fragments. It is indicated for use with external fixator in fractures of femur, tibia, feet, ankle, humerus, forearm, radio and wrist.
It has a blind tip and other tip in nail shape (see figure).

Forms of presentation:
They are placed in double plastic packaging separating the part of Use Instruction.

Quantity of units for packaging:
- Schanz Pin..... 06 units (Ø 3,0 x 100 mm)
- Schanz Pin..... 04 units
- Kirschner Wire ..... 06 units
- Steinmann Wire..... 06 units
- Smooth Wire..... 06 units
- Wire w/ Olive..... 06 units

List of types of Wires available, Codes/Descriptions:

Product Code	DESCRIPTION
04.08.05.08230	Kirschner Wire Ø0,8x230mm
04.08.05.08300	Kirschner Wire Ø0,8x300mm
04.08.05.10100	Kirschner Wire Ø1,0x100mm
04.08.05.10120	Kirschner Wire Ø1,0x120mm
04.08.05.10150	Kirschner Wire Ø1,0x150mm
04.08.05.10230	Kirschner Wire Ø1,0x230mm
04.08.05.10250	Kirschner Wire Ø1,0x250mm
04.08.05.10280	Kirschner Wire Ø1,0x280mm
04.08.05.10300	Kirschner Wire Ø1,0x300mm
04.08.05.12230	Kirschner Wire Ø1,2x230mm
04.08.05.12250	Kirschner Wire Ø1,2x250mm

04.08.05.12300	Kirschner Wire Ø1,2x300mm
04.08.05.15150	Kirschner Wire Ø1,5x150mm
04.08.05.15230	Kirschner Wire Ø1,5x230mm
04.08.05.15250	Kirschner Wire Ø1,5x250mm
04.08.05.15300	Kirschner Wire Ø1,5x300mm
04.08.05.15400	Kirschner Wire Ø1,5x400mm
04.08.05.18230	Kirschner Wire Ø1,8x230mm
04.08.05.18250	Kirschner Wire Ø1,8x250mm
04.08.05.18300	Kirschner Wire Ø1,8x300mm
04.08.05.18400	Kirschner Wire Ø1,8x400mm
04.08.05.20300	Kirschner Wire Ø2,0x300mm
04.08.06.10230	Kirschner Wire Ø1,0x230mm
04.08.06.10300	Threaded Kirschner Wire Ø1,0x300mm
04.08.06.15230	Threaded Kirschner Wire Ø1,5x230mm
04.08.06.15300	Threaded Kirschner Wire Ø1,5x300mm
04.08.06.18300	Threaded Kirschner Wire Ø1,8 x 300mm
04.08.07.20160	Steinmann Wire Ø2,0x160mm
04.08.07.20230	Steinmann Wire Ø2,0x230mm
04.08.07.20250	Steinmann Wire Ø2,0x250mm
04.08.07.20300	Steinmann Wire Ø2,0x300mm
04.08.07.20310	Steinmann Wire Ø2,0x310mm
04.08.07.20400	Steinmann Wire Ø2,0x400mm
04.08.07.25160	Steinmann Wire Ø2,5x160mm
04.08.07.25230	Steinmann Wire Ø2,5x230mm
04.08.07.25250	Steinmann Wire Ø2,5x250mm
04.08.07.25280	Steinmann Wire Ø2,5x280mm
04.08.07.25300	Steinmann Wire Ø2,5x300mm
04.08.07.25400	Steinmann Wire Ø2,5x400mm
04.08.07.30230	Steinmann Wire Ø3,0x230mm
04.08.07.30250	Steinmann Wire Ø3,0x250mm
04.08.07.30300	Steinmann Wire Ø3,0x300mm
04.08.07.35230	Steinmann Wire Ø3,5x230mm
04.08.07.35250	Steinmann Wire Ø3,5x250mm
04.08.07.35300	Steinmann Wire Ø3,5x300mm
04.08.07.40160	Steinmann Wire Ø4,0x160mm
04.08.07.40230	Steinmann Wire Ø4,0x230mm
04.08.07.40250	Steinmann Wire Ø4,0x250mm
04.08.07.40300	Steinmann Wire Ø4,0x300mm
04.08.07.45230	Steinmann Wire Ø4,5x230mm
04.08.07.45300	Steinmann Wire Ø4,5x300mm
04.08.07.50200	Steinmann Wire Ø5,0x200mm
04.08.07.50230	Steinmann Wire Ø5,0x230mm
04.08.07.50250	Steinmann Wire Ø5,0x250mm
04.08.07.50300	Steinmann Wire Ø5,0x300mm
04.08.08.20230	Threaded Steinmann Wire Ø2,0x230mm

04.08.08.20300	Threaded Steinmann Wire Ø2,0x300mm
04.08.08.25230	Threaded Steinmann Wire Ø2,5x230mm
04.08.08.25300	Threaded Steinmann Wire Ø2,5x300mm
04.08.08.30230	Threaded Steinmann Wire Ø3,0x230mm
04.08.08.30300	Threaded Steinmann Wire Ø3,0x300mm
04.08.08.35230	Threaded Steinmann Wire Ø3,5x230mm
04.08.08.35300	Threaded Steinmann Wire Ø3,5x300mm
04.08.08.40230	Threaded Steinmann Wire Ø4,0x230mm
04.08.08.40300	Threaded Steinmann Wire Ø4,0x300mm
04.08.08.45230	Threaded Steinmann Wire Ø4,5x230mm
04.08.08.45300	Threaded Steinmann Wire Ø4,5x300mm
04.08.08.50230	Threaded Steinmann Wire Ø5,0x230mm
04.08.08.50300	Threaded Steinmann Wire Ø5,0x300mm
04.08.09.10300	Holed Wire 1,0x300mm w/ 3 Holes
04.08.09.20300	Holed Wire 2,0x300mm w/ 3 Holes
04.08.09.25300	Holed Wire 2,5x300mm w/ 3 Holes
04.08.10.20300	Holed Wire 2,0x300mm w/ 4 Holes
04.08.10.25300	Holed Wire 2,5x300mm w/ 4 Holes
04.08.11.25300	Holed Wire 2,5x300mm w/ 2 Holes
04.08.12.10230	Kirschner Wire – Double Tip Ø 1,0 x 230mm
04.08.12.15230	Kirschner Wire – Double Tip Ø 1,5 x 230mm
04.08.13.20230	Steinmann Wire Ø2,0x230mm - Double Tip
04.08.13.25230	Steinmann Wire Ø2,5x230mm - Double Tip
04.25.08.25080	Schanz Pin Ø 2,5x80mm
04.25.08.25100	Schanz Pin Ø 2,5x100mm
04.25.08.30080	Schanz Pin Ø 3,0x80mm
04.25.08.30100	Schanz Pin Ø 3,0 x 100 mm
04.25.08.35080	Schanz Pin Ø 3,5x80mm
04.25.08.35100	Schanz Pin Ø 3,5x100mm
04.25.08.40090	Schanz Pin Ø 4,0x90mm
04.25.08.40130	Schanz Pin Ø 4,0x130mm
04.25.08.40150	Schanz Pin Ø 4,0x150mm
04.25.08.40170	Schanz Pin Ø 4,0x170mm
04.25.08.48150	Schanz Pin Ø 4,8x150mm
04.25.08.48160	Schanz Pin Ø 4,8x160mm
04.25.08.48170	Schanz Pin Ø 4,8x170mm
04.25.08.48200	Schanz Pin Ø 4,8x200mm
04.25.08.50160	Schanz Pin Ø 5,0x160mm
04.25.08.50200	Schanz Pin Ø 5,0x200mm
04.25.09.45160	Conical Schanz Pin Ø 4,5x160mm
04.25.09.45200	Conical Schanz Pin Ø 4,5 x 200 mm
04.25.09.48200	Conical Schanz Pin Ø 4,8 x 200 mm
04.25.09.50200	Conical Schanz Pin Ø 5,0x200 mm
04.08.15.15400	Wire with Olive Ø 1,5
04.08.15.18400	Wire with Olive Ø 1,8

04.08.14.15400	Smooth Wire Ø 1,5
04.08.14.18400	Smooth Wire Ø 1,8

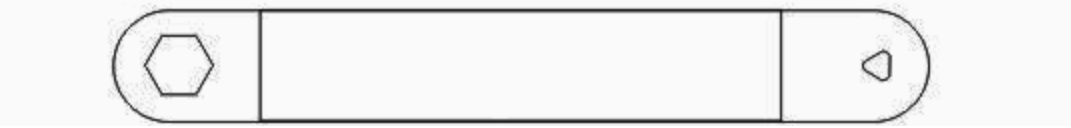
IMPORTANT

For implantation of the Smooth Metallic Wires or Sterile Threaded for Bone Fixation, is need the use of a bone puncher that is not supplied by the company.

In general, these punchers are part of instrumental of routine of hospitals and orthopedic clinics, for orthopedic surgical procedures.

We suggest the use of the following models of punchers:

- System for Bone Drilling Power Pro, brand LINVATEC;
- Osteopower System of Bone Drilling for Micro Surgery, brand Zimmer;
- Pneumatic System for Bone Drilling SmartDriver 6640, brand MicroAire;
- Electric System for Drilling SERIE 7000, model 7500, band MicroAire;
- Micro motors Electric System for Drilling SERIE 1000 E, brand MicroAire;
- For application of the Schanz Pin is need the use of a special key for application of them:



Wrench

The wrench for application of the Schanz Pin should be acquired separately.
For perfect fit, the wrench should be purchased from MDT.

Contraindications

- Patients with bone infection or not, acute or chronic (relative contraindication, to the medical criterion);
- Patients with impaired general state, unable to be submitted to a surgical procedure;
- Sensibility to foreign bodies. In case of suspicion, tests should be performed in the patient;
- Poor bone quality;
- Young patients who perform sportive activities or obese patients;
- Certain allergies to stainless steel. In this case the doctor must apply exams and pertinent tests and evaluate the relevance of performing surgery;
- Particular conditions of the patient: senility, alcoholism and infections. These conditions should be carefully investigated by the surgeon, which should alert the patient about risks from these particularities;
- Devices reuse;

Adverse Effects – Implantation Risks

- Absence or delay of union resulting in implant breakage;
- Deformation or fracture of the implant;
- Loosening or displacement of the implant;
- Pains or discomfort due to the product;
- Damages to nerves due to surgery;
- Bone necrosis or soft tissues;
- Improper cure, and;
- Bone fracture and pains postoperative.

Precautions

- The medical team should verify of the implants integrity to be used the end of the sterilization process and before its use too;
- The surgeon should not initiate the clinical use of the wires before complete reading these instructions for use. Additionally, Should use the wires in specialized environments (ambulatory or operating rooms). The medical team should verify the wires and instrumentals integrity at the end of the sterilization process and before the use;

- The wires should be used by qualified professionals and familiarized with orthopedic implants procedures;
- There is need of periodic medical monitoring to observe possible changes in the implant conditions and adjacent bones. Only monitoring can detect possible release or breakage of components or occurrence of osteolysis;
- Necessary is for the patient visit your doctor regularly to perform exams, as X-Ray to assess the implant condition, to analyze it is whether loose, broken or causing destruction of bone tissue.

Information to the patient:
The patient should be informed about:

- All the postoperative restrictions, particularly those related to sports and occupational activities;
- The fact that complications or failures in osteosynthesis are more likely to occur in:
  - ✓ Patients with functional expectative beyond what can be promoted by the surgery;
  - ✓ Patients with systemic or local diseases that cause bone disorders such as osteoporosis.
- The related information in the topics **Indications**, **Contra indications**, **Adverse Effects**, **Precautions** and **Warnings**;
- There is need of periodic medical monitoring to observe possible changes in the implant conditions and adjacent bones. Only monitoring can detect possible release or breakage of components or occurrence of osteolysis. It is need the for the patient visit your doctor regularly to perform exams, as X-Ray to assess the implant condition, to analyze it is whether loose, broken or causing destruction of bone tissue.
- When the components loosen and osteolysis occurs and not is performed review surgery, can result in progressive loss of periprosthetic bone stock;
- When release is found, breakage or destruction of bone tissue is needed surgical intervention for implant removal, if it has already fulfilled its function, or replacement of the implant in the case of permanent implants;
- The patient should be instructed not to submit to Magnetic Resonance Examinations. The metallic materials as well as stainless steel do not allow X-Ray passage, causing interference with the radiographs interpretation of conventional incidences.

Warnings:
NON STERILE PRODUCT
SINGLE USE PRODUCT – DO NOT REUSE
STERILIZE BEFORE USE
STERILIZATION METHOD: AUTOCLAVE

- Must be correctly sterilized before use and correctly handled to avoid contamination;
- SINGLE USE Product. After use must not be reused in no hypothesis;
- Transport and storage, should be observed the following conditions:
  - ✓ Wires should not be thrown or beaten;
  - ✓ Should not be put excess weight on the parts;
  - ✓ The storage place must be sheltered from direct light to preserve the packaging and labeling, free of humidity and contaminant substances;
- The clinical results and the durability of the implants are extremely dependents on an accurate surgical technique;
- Handle the implant with care;
- The patient should do periodic medical monitoring to verify the conditions of the implant and adjacent bones;
- Components of other manufacturers should not be used;
- Implants should not be modified, scratched or bent (except when the surgical technique used recommends modeling during surgery). Notches or scratches caused to the implants during the surgery can contribute to its fracture.

Special cares and clarifications about the medical product
If the implants are not removed, they can cause the following complications:

- Corrosion, abrasion or erosion of device with localized tecidular reaction or pain;
- Migration resulting in lesion of soft tissue or joints;
- Risk of additional lesion of an accidental trauma in postoperative period;
- Laxity or disassembly of the device, causing lesions;
- Curvature, laxity or breaking of the device which can make impractical or difficult the removal;
- Pain, discomfort or abnormal sensations due to the device;
- Possible increasing of infection risk;
- Bone loss due to a protection of effort.

THE DECISION TO REMOVE IMPLANTS IS OF THE SURGEON IN CHARGE AND WHEREVER POSSIBLE, SHOULD BE CONSIDERED THE COMPLIANCE OF OBJECTIVE WHICH WAS PROPOSED.

- The wires should not be used together with ancillaries and instrumentals of other manufacturer;
- The opening of the packaging for surgical use should be done by the nursing team, enabled for this procedure;
- Never reuse an implant, because even without appearance of damage, previous efforts can reduce its lifetime;

Contamination Risk

Considering that the wire come in contact with tissues and corporal fluids, there is the risk of biological contamination and transmission of viral diseases, such as hepatitis and HIV, etc. Therefore, the explanted wires should be treated as contaminants potentially materials.

Product Discard

After patient removing, discard the wire, because these parts should **not be reused.**

The explanted implants or by accident are defective, should be unusable for use before of the discard. It is recommended that the parts be cut, curved or rasped for its destruction.

For discard the explanted wires, follow the legal local procedures of country, for dispose of products contaminants potentially.

Use Instructions

- The surgical techniques vary according to the surgeon choice, which is responsible by the method, type and dimension of products to be used, as well as, the evaluation criteria of the surgical results.
- The user is responsible to guarantee the use of the proper sterilization process and verification of sterility of all devices in any process phase.
- These devices are manufactured and supplied non sterilized in plastic packaging, which should be removed before of the sterilization process, because they are not appropriate to this procedure.
- Consult Operation Manual of the puncher equipment about drilling technique and warnings.

Additional Information:

Consult the recommended bibliography for more information about use and purpose of wires and pins.

Should be protected the proportioned fixation by the device in step postoperative until complete the curative phase. It is need to comply strictly with the postoperative regimen prescribed by doctor to prevent that the patient suffers adverse effects, resulting from implant placement.

The foreign material implantation in organic tissues can incite inflammatory response that can happen, for example, due to presence of residues from implants (as metallic residues). They can cause response histiocytic type granuloma of strange body causing bone destruction associated or not at implant loosening;

Sensibility or atopic to the metal can be found after the implantation of orthopedic devices. In case of adverse effects, the implant should be removed.

Cleaning

When the products are used for the first time, they should be removed from its package and cleaned with alcohol for medical use at 70%.

After cleaning, the products must be rinsed with sterile distillate water and dried with cleaning cloth that does not release fibers.

Important

Detergents with chlorine free or sodium hydroxide **should not** be used.

Sterilization

Before the surgical use, the products should be cleaned as described and sterilized by autoclave following a validated sterilization procedure.

The **recommended** sterilization cycle is:

Method	Cycle	Temperature	Exposition Time
Steam	Pre-Vacuum	132º - 135º C [270º - 275º F]	Minimum 10 minutes

The selected sterilization process, in any case, must ensure the theoretical probability of presence of microorganism vital to a maximum of 1 $x10^{6}$ (S.A.L. [Sterility Assurance Level] = 10^{-6}).

The user is responsible by the guarantee of use of a proper process of sterilization and verifying of sterility of all devices, in any process phase.

Criteria of Disqualifying of the product

Product should be sterilized in autoclave before use and its packaging should be removed because it is not proper for steam sterilization procedure.

The product should be discarded when its packaging is violated and presents damage in its surface.

Traceability

To ensure the traceability of the implanted product, and comply with the requirements of the sanitary surveillance, it is recommended that the surgeon in charge by implantation notified to the Distributor with the following information regarding to the implanted product, patient and surgery:

- Surgeon's Name;
- Surgery Date;
- Name of Patient who received the implant;
- Code of Product;
- Number of Batch;

Engraving:

Smooth Metallic Wire/Threaded for Bone Fixation with physical space above 2.0 mm receives electronic engraving with the following information:

- Company Name;
- Manufacturing Batch;
- Code.

The packaging of wires has label with Code and Bach of the product, which should be recorded in the patient formulary, to guarantee the traceability.

Storage and Transport

In the transport and storage should be observed the following conditions:

- The wires should not be thrown or beaten;
- It should not be put excessive weight on the implant;

- The storage place must be sheltered from direct light to preserve the packaging and labeling, free of humidity and contaminant substances.
- Always keep the implants in their original packaging until the moment for use, under the responsibility of the medical/hospital team designated for this purpose.
- Manufacturing date, validity term and batch number: see label.

Recommended Bibliography:

MANUAL DE OSTEOSÍNTESIS – Técnicas Recomendadas por El grupo de La AO – 3ª. Edición, Allgöwer, M., Ed.: Springer Verlag Ibérica – 1993;

PRINCÍPIOS AO DO TRATAMENTO DE FRATURAS - AO PUBLISHING
1ª Edição, Ruëdi, T.P. & Murphy, W.M., Ed.: Artmed 2002;

AO AISI Principles in Spine Surgery AO Publishing, M. Aebi; J.S. Thalgott; J.K. Webb
Ed. Springer Verlag Berlin Heidelberg New York – 1998;

Other information

Manufactured and distributed by:

MDT – Indústria Comércio Importação e Exportação de Implantes SA.
Avenida Brasil, nº 2983 – Distrito Industrial – Rio Claro/ SP – Brasil
CEP: 13505-600
Phone/ Fax: (55-19) 2111-6500
Technical Responsible: Miguel Lopes Monte Júnior – CREA 0601150192

Review: 00
Issue: February 22nd, 2005
Registration ANVISA #: 10417940026

ALERT
INSTRUCTIONS FOR USE

These INSTRUCTIONS FOR USE are not available in printed form, they are available at the website of the manufacturer www.mdt.com.br.

The INSTRUCTIONS FOR USE on the website are indexed by REGISTRATION/ CADASTRE ANVISA´s NUMBER and its TRADE NAME of the product, informed at the label of the product purchased.

All the INSTRUCTIONS FOR USE provided on the website have the identification of the revision and date of emission of the document. The user must pay attention to the correct version (revision and date of emission) of the document regarding the MANUFACTURING DATE informed at the label of the product purchased.

If it is interest to the user, the INSTRUCTIONS FOR USE may be provided in printed form, with no extra cost and the request of the same shall be held by the SAC (Customer Service Department) manufacturer, as following:

Customer Service Department:

Telephone: +55 19 2111.6500

FAX: +55 19 2111.6500

http://www.mdt.com.br

Avenida Brasil, 2983 – Distrito Industrial CEP: 13505-600 | Rio Claro – São Paulo – Brasil

Opening Hours: 8 AM to 5 PM, from Monday to Friday, except holidays.

MDTImplantes

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